

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and)	
BAYER HEALTHCARE)	
PHARMACEUTICALS INC.,)	
)	
Plaintiffs,)	C.A. No. 13-1272 (RGA)
)	
v.)	
)	
WATSON LABORATORIES, INC.,)	
)	
Defendant.)	

MERCK & CIE, BAYER PHARMA AG and)	
BAYER HEALTHCARE)	
PHARMACEUTICALS INC.,)	
)	
Plaintiffs,)	C.A. No. 13-978 (RGA)
)	
v.)	
)	
WATSON LABORATORIES, INC.,)	
)	
Defendant.)	

**STIPULATION AND ORDER REGARDING
INFRINGEMENT AND CLAIM CONSTRUCTION**

Plaintiffs Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, “Bayer”) and Defendant Watson Laboratories, Inc. (“Watson”) hereby stipulate and agree as follows:

1. On or about April 22, 2013, Watson notified Bayer of its filing of Abbreviated New Drug Application (“ANDA”) No. 203594 with the U.S. Food and Drug Administration (“FDA”), which, along with all amendments and supplements thereto, seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Bayer’s Safyral® product (“Watson’s Safyral® ANDA Product”).

2. On June 4, 2013, Bayer filed its Complaint for infringement of U.S. Patent No. 6,441,168 (the "'168 patent") under 35 U.S.C. § 271(e)(2). Bayer further alleged that the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's Safyral® ANDA Product would infringe one or more claims of the '168 patent.

3. On or about June 19, 2013, Watson notified Bayer of its filing of ANDA No. 203593 with the FDA, which, along with all amendments and supplements thereto, seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Bayer's Beyaz® product ("Watson's Beyaz® ANDA Product").

4. On July 23, 2013, Bayer filed its Complaint for infringement of the '168 patent under 35 U.S.C. § 271(e)(2). Bayer further alleged that the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's Beyaz® ANDA Product would infringe one or more claims of the '168 patent.

5. Watson admits and stipulates that Watson's Safyral® and Beyaz® ANDA Products would, if approved by the FDA and manufactured, used, offered for sale, sold, and/or imported into the United States, infringe claim 4 of the '168 patent, assuming that claim is not invalid and is enforceable.

6. Accordingly, Bayer will not be required to prove at trial or any other hearing in these actions that Watson's Safyral® and Beyaz® ANDA Products infringe claim 4 of the '168 patent, and Bayer will not assert against Watson any other claim of the '168 patent at trial or any other hearing in these actions.

7. The counterclaims asserted by Watson in Civil Action Nos. 13-978 (D.I. 11 at 13) and 13-1272 (D.I. 11 at 13) with respect to non-infringement of claim 4 of the '168 patent are

hereby dismissed with prejudice and the counterclaims with respect to non-infringement of all other claims of the '168 patent are hereby dismissed as moot without prejudice.

8. Bayer and Watson agree and stipulate to the following claim construction for claim 4 of the '168 patent:

“with 2 theta values of 6.5, 13.3, 16.8, and 20.1 (Type I)” shall be constructed as “with 2 theta values of 6.5, 13.3, 16.8, and 20.1 within the normal experimental error of X-ray powder diffraction of +/- 0.20 degrees.”

9. The parties agree that the Markman hearing scheduled for May 29, 2014 may be taken off calendar.

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February 19, 2014

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**[PROPOSED] ORDER REGARDING INFRINGEMENT AND
CLAIM CONSTRUCTION OF U.S. PATENT NO. 6,441,168**

In view of the parties' foregoing stipulations, it is hereby **ORDERED**:

1. Defendant Watson Laboratories, Inc.'s ("Watson") filing of ANDA Nos. 203593 and 203594 constituted an act of infringement of claim 4 of U.S. Patent No. 6,441,168 (the "'168 patent"), assuming the claims are not invalid and are enforceable. Furthermore, the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's Safyral® ANDA Product and/or Watson's Beyaz® ANDA Product would infringe claim 4 of the '168 patent, assuming the claims are not invalid and are enforceable.

2. The foregoing finding of infringement does not preclude Watson from contesting the validity or enforceability of claim 4 of the '168 patent.

3. The counterclaims asserted against Plaintiffs by Watson with respect to non-infringement of claim 4 the '168 patent by Watson's Safyral® and Beyaz® ANDA Products are hereby dismissed with prejudice and the counterclaims with respect to non-infringement of all other claims of the '168 patent are hereby dismissed as moot without prejudice.

4. The term "with 2 theta values of 6.5, 13.3, 16.8, and 20.1 (Type I)" is hereby construed to mean "with 2 theta values of 6.5, 13.3, 16.8, and 20.1 within the normal experimental error of X-ray powder diffraction of +/- 0.2 degrees."

IT IS SO ORDERED:

UNITED STATES DISTRICT JUDGE

DATED: _____